

**REMARKS*****Request That the November 16, 2007 Paper be Correctly Characterized as a "Restriction Requirement" Rather Than a "Non-Final Rejection"***

In the Office Action Summary the Examiner has checked box 6, indicating that claims 12-26 have been rejected, rather than box 8, which would indicate that the claims are subject to a restriction and/or election requirement. The remainder of the document clearly sets forth a restriction requirement, and no grounds for rejection are anywhere stated. Accordingly, it is believed that the Examiner inadvertently checked box 6 when box 8 was intended.

However, as a result of characterizing this November 16, 2007 Paper as a "non-final rejection", it is believed that the document has been entered into the Patent Office database as a "non-final rejection," as indicated by the characterization of this document in PAIR under Document Code "CTNF" and under Document Description as "Non-Final Rejection." It is understood that this error, if not corrected, can have a significant impact on the prosecution of this application, and an amendment and response will be expected rather than the present Response to Restriction Requirement.

It is respectfully requested that the Examiner take whatever steps are needed to correct this error so that the November 16, 2007 Paper is *properly characterized* throughout the US Patent and Trademark Office records as a restriction requirement.

***Election in Response to Election/Restriction Requirement***

In response to the Elections/Restrictions requirement set forth beginning at page 2 of the November 16, 2007 Paper, Applicant hereby elects the invention of Group III, claims 19-26, "drawn to various method procedures drawn to the administration of candesartan or a pharmaceutically acceptable salt thereof and rosuvastatin or a pharmaceutically acceptable salt thereof." In accordance with this election, non-elected claims 12-18 have been *newly* cancelled (claims 1-11 having been previously cancelled) without prejudice to Applicant's right to prosecute the subject matter thereof in one or more divisional applications. Although *this* election has been made without traverse, Applicant does not thereby acknowledge or

otherwise imply its agreement with the Examiner's characterization of the teaching and/or relevance of the Otake *et al.* reference.

***Response to Election of Species Requirements***

Beginning at page 4 of the November 16, 2007 Restriction Requirement, specifically the paragraph bridging pages 4 and 5, it is stated that "within the method species (claims 19-26), applicant must *elect either* (1) a method of preventing or treating atherosclerosis, (2) a method of preventing cardiovascular events, (3) a method of preventing or treating an inflammatory disease or condition, (4) a method of inhibiting expression of (i) CD40 or (ii) metalloproteinases (MMPs) or (iii) LOX-1, or (5) a method of treating atherosclerosis" (emphasis added). In response to this requirement for an election "within the method species" of claims 19-26, Applicant elects the first-stated species, "(1) a method of preventing or treating atherosclerosis," which is claim 19. In accordance with this election of species, claims 20-26 have been designated as withdrawn.

In that same paragraph, however, the Examiner goes on to note that "Applicant must elect one specific and exact component for inhibition, e.g., *a method of inhibiting expression of LOX-1*" (emphasis in original)." It is understood that this only applies in the event Applicant had elected "method species" (4), *i.e.*, claims 23-26, which recite inhibition of the expression of CD40 and/or metalloproteinases or LOX-1. Since no such inhibition is recited in elected species (1), *i.e.*, claim 19, it is understood that this further requirement does not apply.

The remainder of that paragraph at the top of page 5 is specifically said to apply "in the occasion that applicant elects (3)" [inflammatory diseases and conditions], which is also understood not to apply to Applicant's election of species (1).

The undersigned is somewhat confused, however, by the next three paragraphs (middle three paragraphs on page 5) wherein the Examiner states:

For instance, if applicant elects a method species for examination on the merits, a proper election must set forth a species of method that falls within the disclosed genus, such as, e.g., a method for preventing, a method for treating, a method for inhibiting expression, etc. Election of a genus without setting forth a single, specific specie within the genus will be held non-responsive.

The following claims are generic: claims 12-26.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claims provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please see MPEP §809.02(a).

(Restriction Requirement at page 5).

Method claims 19-26 have already been characterized as “method species (claims 19-26)” [page 4, fifth line from the bottom] and Applicant was requested to elect a species from one of the species (1) through (5) as recited in that paragraph bridging pages 4 and 5. In compliance with this requirement for species election, Applicant has already elected the species “(1) a method of preventing or treating atherosclerosis,” which is coextensive with what the Examiner has characterized as “method species” claim 19. This is inconsistent with the re-characterization of claims 12-26 as each being “generic” in the middle of page 5.

Thus, it is not clear what more the Examiner is requesting in the middle of page 5, and to the extent this constitutes a *further* requirement for election of species, it is respectfully traversed as not being clear. However, the Examiner states that “election of a genus without setting forth a single, specific specie within the genus will be held non-responsive.” In a good faith effort to avoid the consequences of a non-responsive election, Applicant will presume that the further election of species being requested is between the method for preventing and the method for treating encompassed within elected species of claim 19. If this presumption is correct, Applicant hereby elects the “species” of “method of treating.” However, since Applicant is not clear as to whether this further election is being requested, this election is made with traverse, and claim 19 has been left as previously presented, pending clarification.

#### ***Claim Amendments***

As noted above, claims 12-18 are newly cancelled above as being directed toward the non-elected inventions of Groups I and II. The cancellation of these claims is without prejudice to Applicant’s right to prosecute the subject matter thereof in one or more divisional applications.

Claims 19-26 are within elected Group III and therefore have been retained. Pursuant to the Examiner election of species requirement, the method species of claim 19 has been elected, and method claims 20-26 have been indicated as withdrawn. However, it is not clear whether this is a “provisional” election whereupon additional method species will be examined upon finding that claim 19 is allowable. One might so presume from the penultimate paragraph on page 5. However, each of method claims 19-21 and 23-26 is independent and there is no method claim that encompasses each of these claims upon which they could be made dependent. If in fact a “provisional” election was not the Examiner’s intent, upon clarification from the Examiner Applicant will cancel claim 20-26 as being non-elected. Inasmuch as Applicant is unclear as to whether the Examiner is intending to require a further election of species within elected claim 19, claim 19 has not been amended.

Claims 1-11 were previously cancelled. Therefore, after entry of the above amendments, claims 19-26 remain pending in this application with claims 20-26 being designated as “withdrawn.”

Correction of the mischaracterization of the November 16, 2007 restriction requirement as a non-final rejection is respectfully requested, as well as clarification of the request for election of species as noted above.

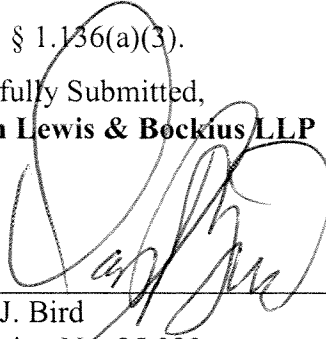
#### ***Supplemental Information Disclosure Statement***

The Examiner’s attention is called to the Supplemental Information Disclosure Statement submitted herewith citing and providing a copy of WO02/058731. This documents, as well as other documents previously cited in this application, were referenced in the examination report from the European Patent Office the European patent application corresponding to the present application. **A copy of that European Patent Office examination report dated December 13, 2007 is also submitted herewith for the Examiner’s information.**

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Director is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required,

including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,  
**Morgan Lewis & Bockius LLP**



Date: **February 15, 2008**  
Morgan Lewis & Bockius LLP  
Customer No. **09629**  
1111 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
Tel. No.: 202-739-3000  
DJB:

By:

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Donald J. Bird  
Registration No. 25,323  
Tel. No.: (202) 739-5320  
Fax No.: (202) 739-3001